REMARKS

The Office Action of January 18, 2006, has been received and reviewed.

Claims 1-22 are currently pending and under consideration in the above-referenced application. Of these, claims 1-16 and 18-22 stand rejected. Claim 17 is directed to subject matter that is "free of the prior art."

Reconsideration of the above-referenced application is respectfully requested.

Rejections under 35 U.S.C. § 102

Claims 1-3, 7-16, and 18-22 stand rejected under 35 U.S.C. § 102(b) for being directed to subject matter that is purportedly anticipated by the subject matter described in U.S. Patent 5,080,895 to Tokoro (hereinafter "Tokoro").

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Notably, independent claim 1 of the above-referenced application is directed to methods for causing treated animals to elicit T-cell mediated immune responses. Such methods include administering to the treated animal a quantity of a composition that includes an extract of an egg from a non-mammalian source animal, with the extract comprising transfer factor. The transfer factor, which is generated by the source animal in response to at least one antigenic agent, is present in a concentration that exceeds that present within the egg. In addition, the transfer factor is present in a sufficient quantity to initiated the T-cell mediated immune response in the treated animal.

It has been asserted that Tokoro discloses methods for causing chickens to generate transfer factor. It is respectfully submitted that Tokoro neither expressly nor inherently describes a method for causing chickens to generate transfer factor that is present in their eggs.

In this regard, it should be noted that the disclosure of Tokoro is limited to exposing a chicken to certain antigens. Contrary to the apparent assertion that has been made at page 4 of

the Office Action of January 18, 2006, Tokoro does not expressly or inherently describe that the compositions disclosed therein were obtained from chickens that were vaccinated with Newcastle Disease Virus (NDV). Rather, the disclosure of Tokoro is limited to exposing chickens to three antigens: the 987P, K88, and K99 antigens of enterotoxic *E. coli* (ETEC). As has been demonstrated, none of these three antigens results in the generation of transfer factor. Instead, these three antigens merely result in the presence of antibodies (from B-cells) and a substance referred to in both Tokoro and the art as a "transfer factor-like component" in eggs that are laid by the chicken. Col. 5, lines 4-6; col. 5, lines 14-22; col. 5, line 29, to col. 6, line 7.

Although a "transfer factor-like component" may, purportedly, passively transfer delayed-type hypersensitivity to a treated animal, one of ordinary skill in the art would readily understand from the disclosure of Dunnick, W., et al., "Lack of Antigen Fragments in Guinea Pig Transfer Factor-like Activity, Clin. Immunol. and Immunopathol. 17: 55-65 (1980), at page 65, that a "transfer factor-like component" is not transfer factor. Although a "transfer factor-like" substance, such as the "unknown food factor" described in U.S. Patent 4,402,938 to Collins et al. (*see, e.g.,* Tokoro, col. 7, lines 51-53) or nucleosides, which have molecular weights of less than about 2,000 Da, may cause a non-specific improvement in treated animal's immune system response that could be viewed superficially as similar to the way that immune system would respond to transfer factor, these and other "transfer factor-like" substances are incapable of causing the immune system of a treated animal to elicit a specific response (*i.e.,* a response to a particular antigen), while transfer factor can elicit a specific response from the immune system of a treated animal.

In any event, Tokoro clearly indicates to those of ordinary skill in the art that the "transfer factor-like" substance described therein is not transfer factor. Specifically, Tokoro provides that "the immunological functions of the transfer factor-like component . . . are not known" (col. 7, lines 44-47). As evidenced by much of the art that has been made of record in the above-referenced application, the immunological functions of transfer factor were, in contrast, known at the time the application that eventually issued as Tokoro was filed.

While the Office acknowledges that chickens could be raised in a germ-free, or sterile, environment, it has been asserted that, "[i]f chicken accommodations were sterile, then no

vaccination would ever be required." Office Action of January 18, 2006, page 3. This is an inherency argument. M.P.E.P. § 2112 explains inherency as follows:

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic. *In re Rijckaert,* 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) . . . 'To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill . . .'' *In re Robertson,* 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1991).

Thus, in order for Tokoro to inherently disclose a method for causing a treated animal to elicit a T-cell mediated immune response, obtaining transfer factor from eggs, transfer factor *must* have been present in eggs that were collected in Tokoro. That means that the chickens from which eggs are collected, or the eggs themselves, must have been exposed to antigens that would have caused a T-cell mediated immune response.

There are at least two reasons that transfer factor is not inherently present in eggs that are collected in accordance with the teachings of Tokoro. First, the disclosure of Tokoro is limited to administering three antigens, the 987P, K88, and K99 antigens of ETEC that are known to elicit a B-cell response. The administration of the 987P, K88, and K99 antigens of ETEC would not result in the elicitation of a T-cell mediated immune response or the presence of transfer factor in the collected eggs. Macpherson, A.J., et al., "A Primitive T Cell-Independent Mechanism of Intestinal Mucosal IgA Responses to Commensal Bacteria," Science, 28: 2222-2226 (2000); Song, M-K, et al., "Light Chain of Natural Antibody Plays a Dominant Role in Protein Antigen Binding," Biochem. and Biophysical Res. Communications, 268:390-394 (2000); Aramaki, M., et al., "Presence of Activated B-1 Cells in Chronic Inflamed Gingival Tissue," J. Clin. Immunol., 18: 421-429 (1998); Hansen, P.G.C., et al., "The Occurrence and Sources of Natural Antibody in Human Bile and Serum Against the O Antigens of Two *Escherichia coli* Serotypes," Scand. J. Immunol., 32:537-544 (1990); Galili, U., et al., "Interaction between Human Natural Anti-α-Galactosyl Immunoglobulin G and Bacteria of the Human Flora," Infection and Immunity, 56:1730-1737 (1988); Skarnes, R.C., "Humoral

Bactericidal Systems: Nonspecific and Specific Mechanisms," Infection and Immunity, 19:515-522 (1978); Sewell, H.R., et al., "The natural antibody response to *E. coli* includes antibodies of the IgD class," Clin. Exp. Immunol., 31:104-110 (1977), copies of each of which are enclosed.

Further, Tokoro does not disclose that chickens must be exposed to any other antigens, including NDV, as asserted at page 4 of the Office Action dated January 18, 2006. In fact, Tokoro notes, at col. 2, lines 54-60, that animals may be "germ-free," as is well-known in the art. Stated another way, chickens that are born, raised, and housed in controlled (*e.g.,* sterile or otherwise "germ-free") environments could be exposed only to one or more of the three antigens disclosed in Tokoro, without being exposed to any antigens that would cause the chickens to elicit a T-cell mediated immune response. The Office has already acknowledged this possibility by stating, "*[u]nless* Tokoro housed the chickens in a completely sterile environment, one would expect that Tokoro's chickens had had a T-cell immune response to some antigen." Office Action of January 18, 2006, page 4 (emphasis supplied). Tokoro does not provide any indication about whether the chickens were raised in a controlled or sterile environment or a non-sterile environment. As the chickens described in Tokoro could have been raised in a controlled or sterile environment, Tokoro does not inherently describe that chickens were exposed to antigens that would cause a T-cell mediated immune response. Therefore, it is not inherent that transfer factor would have been present in eggs laid by the chickens disclosed in Tokoro.

Due to the possible lack of a T-cell mediated immune response, any eggs collected from the chickens wouldn't necessarily include transfer factor in a quantity adequate for transferring cellular immunity to a mammal *in vivo*. Therefore, compositions that include the extract of an egg that has been collected in accordance with the teachings of Tokoro wouldn't necessarily include an extract that includes at least one type of non-mammalian transfer factor "generated . . . in a T-cell mediated immune response [of a source animal] to at least one antigenic agent," as required by both independent claim 1 and independent claim 20.

Moreover, Tokoro neither expressly nor inherently describes administering a composition that includes transfer factor in a sufficient quantity to initiate a T-cell mediated immune response

in a treated animal, as would be required for Tokoro to anticipate each and every element of independent claim 1 and independent claim 20.

Further, the administration of compositions that include the extract of an egg that has been collected in accordance with the teachings of Tokoro wouldn't necessarily work with a treated animal's immune system "to initiate [a] T-cell mediated immune response *in vivo*," as required by independent claim 20. As noted above, transfer factor is not inherently present in the eggs disclosed in Tokoro. Moreover, as has been explained, Tokoro does not expressly or inherently describe that the composition disclosed therein transfers cellular immunity to a treated animal *in vivo*."

As such, it is clear that the description of Tokoro does not anticipate each and every element of either independent claim 1 or independent claim 20, as would be required to maintain the 35 U.S.C. § 102(b) rejections of independent claims 1 and 20.

Claims 2-3, 7-16, 18, 19, and 22 are each allowable, among other reasons, for depending directly or indirectly from claim 1, which is allowable.

Claim 19 is additionally allowable since Tokoro includes no express or inherent description that there is a sufficient amount of transfer factor in any of the compositions disclosed therein to cause an animal to which the composition is administered to elicit a T-cell mediated immune response *in vivo*.

Claim 22 is further allowable since Tokoro lacks any express or inherent description that administration of an extract of the eggs disclosed therein to a treated animal would enhance the ability of the immune system of the treated animal to elicit an increased T-cell mediated immune response relative to the treated animal's normal T-cell mediated immune response to at least one antigenic agent.

Claim 21 is allowable, among other reasons, for depending directly from claim 20, which is allowable.

Claim 21 is also allowable since Tokoro includes no express or inherent description that there is a sufficient amount of transfer factor in any of the compositions disclosed therein to

cause an animal to which the composition is administered to elicit a T-cell mediated immune response *in vivo*.

Withdrawal of the 35 U.S.C. § 102(b) rejections of claims 1-3, 7-16, and 18-22 is respectfully requested.

Rejections under 35 U.S.C. § 103(a)

Claims 4-6 have been rejected under 35 U.S.C. § 103(a) for being directed to subject matter that is allegedly unpatentable over the subject matter taught in Tokoro, in view of teachings from U.S. Patent 5,840,700 to Kirkpatrick et al. (hereinafter "Kirkpatrick").

The standard for establishing and maintaining a rejection under 35 U.S.C. § 103(a) is set forth in M.P.E.P. § 706.02(j), which provides:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Claims 4-6 are each allowable, among other reasons, for depending directly from claim 1, which is allowable.

Claims 4-6 are additionally allowable because, one of ordinary skill in the art wouldn't have had the benefit of hindsight that the claims and disclosure of the above-referenced application have provided to the Office, which is apparently the sole source of motivation for the assertion that one of ordinary skill in the art would have been motivated to combine teachings relating to obtaining transfer factor from mammalian tissues (Kirkpatrick) with teachings that relate to the presence of a non-transfer factor, transfer factor-like substance in eggs (Tokoro).

It is respectfully submitted that one of ordinary skill in the art wouldn't have been motivated to combine teachings from Tokoro and Kirkpatrick for a number of reasons. First, the teachings of Kirkpatrick are limited to methods for purifying transfer factor that has been obtained conventionally, from the cells of mammals, while the teachings of Tokoro relate to methods for generating antibodies and a "transfer factor-like" component in eggs, with no mention that transfer factor is actually present in the eggs. Thus, one of ordinary skill in the art wouldn't have been motivated to employ the transfer factor purification processes of Kirkpatrick on a composition, such as that disclosed in Tokoro, that is not known to include transfer factor. Second, the teachings of Kirkpatrick relate to a purified product that may be effectively administered to a treated animal non-orally, while the compositions of Tokoro are intended to be administered orally so that they can be used to treat intestinal pathogens. Third, Tokoro plainly teaches that the presence of antibodies in the compositions disclosed therein are beneficial to treated animals, without providing data as to the benefits of the "transfer factor-like" component mentioned therein. If the method of Kirkpatrick were employed on the composition of Tokoro, antibodies would be removed from that composition, negating any proven effect thereof in treating intestinal pathogens.

It is also respectfully submitted that, before the filing date of the earliest application to which a priority claim has been made in the above-referenced application, one of ordinary skill in the art would have no reason to expect the asserted combination of reference teachings to be successful. In particular, one of ordinary skill in the art would have no reasonable expectation from the teachings or suggestions of Tokoro that transfer factor would or could have been collected from eggs. Thus, one of ordinary skill in the art would have had no reason to attempt to purify an extract of an egg obtained in accordance with teachings from Tokoro in the manner taught by Kirkpatrick, let alone any reason to expect that transfer factor could be purified in an amount adequate for transferring cellular immunity to a mammal *in vivo*.

As such, a *prima facie* case of obviousness has not been established against any of claims 4-6, as would be required to maintain the 35 U.S.C. § 103(a) rejections of these claims.

It is respectfully requested that the 35 U.S.C. § 103(a) rejections of claims 4-6 be withdrawn.

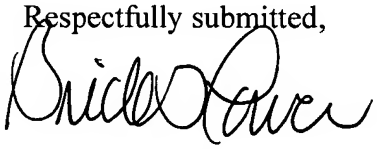
Allowable Subject Matter

The indication that claim 17 is drawn to subject matter that is allowable over the art of record is noted with appreciation. Claim 17 has not been amended to independent form, however, as claim 1, from which it depends, is believed to be allowable.

CONCLUSION

It is respectfully submitted that each of claims 1-22 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,



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